K003362

MAR - 1 2001

510(k) Summary of Safety and Effectiveness

Table1 - Sponsor Information

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Andrea L. Boumis Associate, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Numbers:	Phone: 408.895.3625 Pager: 888.509.6375 Fax: 408.895.2202

Table2 - Device Information

Device Common Name	Programmable Diagnostic Computer
Device Proprietary Name	Astronomer+ with SLD
Device Classification Name	Programmable Diagnostic Computer
Device Classification	Class II DQK 21 CFR 870.1425
Predicate Devices	Carto System; QMS2; CardioCath Lab System; EnSite 3000 Electrophysiology Workstation; Arrhythmia Mapping System
Predicate Device Manufacturer(s)	Biosense, Ltd.; CathData; Prucka Engineering Inc.; Endocardial Solutions, Inc.; Cardiac Pathways Corporation
Predicate Device Reference(s)	K954395; K990058; K960321; K001437; K965066
Predicate Device Proprietary Name(s)	Carto System; QMS2; CardioCath Lab System; EnSite 3000 Electrophysiology Workstation; Arrhythmia Mapping System
Predicate Device Classification Name(s)	Programmable Diagnostic Computer
Predicate Device Classification(s)	Class II DQK 21 CFR 870.1425

Date Summary Was Prepared October 26, 2000.

Description of the Device: This device is a data management system intended for use within a cardiac electrophysiology lab for the creation, maintenance, and review of patient files generated during a typical electrophysiology study. The device consists of a workstation running proprietary software, and catheter interface.

Intended Use: The Astronomer+ System is a computerized system to assist in the diagnosis of complex cardiac arrythmias. The Astronomer+ System is intended to be used to collect, record, and route to display, electrogram (EGM) and electrocardiogram (EKG) signals and other patient data.

Technological Characteristics: The Astronomer+ System is an accessory for the Constellation Catheter. Its function and intended use are similar to several commercially available systems, such as CathData's QMS2, Biosense's Carto System, and Endocardial Solutions' EnSite 3000. Like these other systems, the Astronomer+ system is comprised of a catheter input box (the Switching & Locating Device) and a Computer, running a proprietary GUI (Astronomer+). The system provides data to the physician obtained from the Constellation Catheter and a Roving (or auxiliary) Catheter (typically a quad catheter). The System has two window displays which simultaneously show: Constellation catheter orientation, roving catheter proximity indication and user-defined markers. Additionally, the SLD routes signals received from the Constellation and Roving Catheters 1-to-1 to stand-alone EP recorders for acquisition, storage and display purposes.

Summary of Testing Performed: Tests were performed both in vitro and in vivo to confirm safety and effectiveness. Further, conformance to several recognized standards is maintained.

Table3 - Device Comparison to Predicates

Device	*Astronomer+ with SLD*	Carto System	QMS	EnSite 3000 Electrophysiology Workstation	CardioCath Lab System	Arrhythmia Mapping System
510(k) Reference	This Submission	K954395	K990058	K983456	K960321	K965066
Intended Use	Collection, Storage and Routing of Intracardiac Electrograms and Patient Data	Collection, Storage and Display of intracardiac electrograms	Collection, Storage and Display of intracardiac electrograms	Collection, Storage and Display of intracardiac electrograms	Record ECG, Intracardiac and Pressure recordings	Record, View, and Analyze, Intracardiac (EGM) and Surface (EKG) signals
Manufacturer	BSC/EP Technologies	Biosense, LTD.	CathData	Endocardial Solutions, Inc.	Prucka Engineering Inc.	Cardiac Pathways Corporation
Device Classification	Class II DQK 21 CFR 870.1425	Class II DQK 21 CFR 870.1425	Class II DQK 21 CFR 870.1425	Class II MTD 21 CFR 870.1425	Class II 74 DPS 21 CFR 870.1425	Class II DRF 21 CFR 870.1425

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Ms. Andrea Ruth
Regulatory Affairs
Boston Scientific/EP Technologies, Inc.
2710 Orchard Parkway
San Jose, CA 95134

Re: K003362
Trade Name: Astronomer Plus System
Regulatory Class: II (two)
Product Code: DQK
Regulation: 870.1425
Dated: January 10, 2001
Received: January 11, 2001

Dear Ms. Ruth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K003362

Device Name: **Astronomer+ System**

Indication for Use:

The Astronomer+ System is a computerized system to assist in the diagnosis of complex cardiac arrythmias. The Astronomer+ System is intended to be used to collect, record, and route to display, electrogram (EGM) and electrocardiogram (EKG) signals and other patient data.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

2/28/11

Division of Cardiovascular & Respiratory Devices
510(k) Number K003362